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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,768	01/14/2004	Peter J. Littrup	CD110 (040090-000110US)	5489

33746 7590 10/18/2006

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EXAMINER	
VRETTAKOS, PETER J	

ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 10/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

NT

Office Action Summary	Application No.	Applicant(s)	
	10/757,768	LITTRUP ET AL.	
	Examiner	Art Unit	
	Peter J. Vrettakos	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-23 and 26-28* is/are pending in the application.

4a) Of the above claim(s) *24,25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-23 and 26-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The application is published application number: 2004/0215294. The publication is classified in US 606/21.

The effective filing date of this application is 1-15-03. Pending claims are 20-28. Claim 20 is independent. Elected (without traverse) claims 20-23 and 26-28 are examined below.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20-23 and 26-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Independent claim 20 reads, "circulating a cryogenic fluid through the cryoprobe under physical conditions **near** a critical point of a liquid-vapor system for the cryogenic fluid[.]" The word "near" is contextual and is not sufficiently described in the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 20-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Baust et al. (5,520,682).

Baust discloses a cryotherapy method with liquid nitrogen (col. 6:1-2) used as a cryogen in multiple cryoprobes (figure 1, col. 19:21-22, col. 7:47-49).

Further, cryoprobe dimensions and the use of multiple probes for organ or tumor treatment are provided in col. 7:30-51.

Note: specific references in the patented disclosure below are not limiting to those excerpts. (The Office reserves the right in future actions to apply other excerpts, need be, from the patent.) Further, the rejection might use elements from separate embodiments in the patent to address the claim, mixing and matching. This is appropriate unless the conjectured embodiment (the embodiment created for the rejection using elements from different patented embodiments) destroys the function of that conjectured embodiment.

The patent discloses:

20. A method for cooling material, the method comprising:

positioning an end of a cryoprobe in the material;

circulating a cryogenic fluid through the cryoprobe under physical

conditions near a critical point of a liquid-vapor system for the cryogenic fluid, wherein the critical point defines a point in a phase diagram of the liquid-vapor system where molar volumes are substantially equivalent for liquid and gas,

whereby vapor lock associated with cooling of the cryoprobe is avoided.

The patent does not expressly disclose avoidance of vapor lock as a result of circulating a fluid "near" its critical point. However, the Applicant's "discovery" does not necessarily warrant a patent. MPEP § 2112 reads

> **I. SOMETHING WHICH IS OLD DOES NOT BECOME PATENTABLE UPON THE DIS-COVERY OF A NEW PROPERTY**
>
> "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). >In *In re Crish*, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004), the court held that the claimed promoter sequence obtained by sequencing a prior art plasmid that was not previously sequenced was anticipated by the prior art plasmid which necessarily possessed the same DNA sequence as the claimed oligonucleotides. The court stated that "just as the discovery of properties of a known material does not make it novel, the identification and characterization of a prior art material also does not make it novel."

Applied to the instant case, the Applicant's discovery that a cryofluid such as liquid nitrogen (a prior art composition) circulated "near" its critical point providing the "previously unappreciated property" that vapor lock is avoided, does not render the old composition (a circulating cryofluid such as liquid nitrogen) patentably new to the discoverer/Applicant.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baust et al. (5,520,682).

Baust discloses a cryotherapy method with liquid nitrogen (col. 6:1-2) used as a cryogen in multiple cryoprobes (figure 1, col. 19:21-22, col. 7:47-49).

Further, cryoprobe dimensions and the use of multiple probes for organ or tumor treatment are provided in col. 7:30-51.

Note: specific references in the patented disclosure below are not limiting to those excerpts. (The Office reserves the right in future actions to apply other excerpts, need be, from the patent.) Further, the rejection might use elements from separate embodiments in the patent to address the claim, mixing and matching. This is appropriate unless the conjectured embodiment (the embodiment created for the rejection using elements from different patented embodiments) destroys the function of that conjectured embodiment.

The patent discloses:

20. A method for cooling material, the method comprising:

positioning an end of a cryoprobe in the material;

circulating a cryogenic fluid through the cryoprobe under physical

conditions near a critical point of a liquid-vapor system for the cryogenic fluid, wherein the critical point defines a point in a phase diagram of the liquid-vapor system where molar volumes are substantially equivalent for liquid and gas,

whereby vapor lock associated with cooling of the cryoprobe is avoided.

The patent does not expressly disclose avoidance of vapor lock as a result of circulating a fluid "near" its critical point. However, Baust does disclose circulation of liquid nitrogen at different parameters. The Office asserts that vapor lock avoidance could have been determined through optimization/routine experimentation with the Baust disclosure. MPEP § 2144.05 addresses obviousness of dimensions and parameters through optimization and routine experimentation using the prior art. The motivation to optimize is found at *In Re Peterson*, 315 F.3d at 1330, 65 USPQ2d at 1382 where the courts stated that "[t]he normal desire of scientists or artisans to improve upon what is already generally known **provides the motivation** to determine where in a disclosed set of percentage ranges is the optimum combination of percentages." Again, the Office asserts that in light of Baust and routine experimentation, it would have been determined at the time of the Applicant's invention circulating cryofluid "near" its critical point to avoid vapor lock.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baust et al. (5,520,682) in view of Dobak (5,275,595).

Only Dobak makes obvious 33.5 atm.

Dobak discloses a cryosurgical method with pressures that make obvious 33.5 atm. See patented claim 9. (33.5 atm is "less than 740 psi", *which is less than 51 atm*).

Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Baust in view of Dobak by including into the Baust cryotherapy method, 33.5 atm. The motivation would be to introduce to the Baust method as well-known/published pressure parameter.

Claims 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baust et al. (5,520,682) in view of Gudkin et al. (4,519,389).

Only Gudkin discloses thermoelectric cryoprobes potentially used for electrical ablation.

Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Baust in view of Gudkin by including into the Baust cryotherapy method, electrical ablation. The motivation would be to increase the applicability of the Baust method.

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baust et al. (5,520,682) in view of Stern et al. (5,741,248).

Only Stern discloses injections.

Stern discloses injecting cryosensitive agents use a cryoprobe with the needed structure in conjunction with cryosurgery (see Abstract).

Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Baust et al. (5,520,682) in view of Stern et al. (5,741,248) by including into the Baust cryotherapy method, a cryoprobe capable of injection. The motivation is to increase the number of potential applications of the Baust system/method.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Vrettakos whose telephone number is 571-272-4775. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Roy D. Gibson

ROY D. GIBSON
PRIMARY EXAMINER

Pete Vrettakos
October 16, 2006